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EY DOCKET NO. T2090001	CONFIRMATION NO.
T2090001	1165
EXAMINER	
ROBINSON, BINTA M	
RTINIT	PAPER NUMBER
	THE ENTHUMBER
1023	
AILED: 09/13/200	4
	ROBINSON RT UNIT 1625

Please find below and/or attached an Office communication concerning this application or proceeding.

<u> </u>				
• * *	Application No.	Applicant(s)		
Office Action Summan	10/800,740	CHE ET AL.		
Office Action Summary	Examiner	Art Unit		
	Binta M Robinson	1625		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
Status				
1) Responsive to communication(s) filed on				
2a)☐ This action is FINAL . 2b)☒ This	action is non-final.			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims				
 4) Claim(s) 1-14 is/are pending in the application 4a) Of the above claim(s) 3-5 is/are withdrawn 5) Claim(s) is/are allowed. 6) Claim(s) 1-4 and 6-14 is/are rejected. 7) Claim(s) 5 is/are objected to. 8) Claim(s) are subject to restriction and/o 	from consideration.			
Application Papers				
9)☐ The specification is objected to by the Examiner.				
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
Attachment(s)				
1) Notice of References Cited (PTO-892)	4) Interview Summary			
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/2/20004. 	Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate Patent Application (PTO-152)		

Application/Control Number: 10/800,740

Art Unit: 1625

DETAILED ACTION

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not make even a mere assertion that there are known polymorphs of torsemide. The specification also does not disclose any physical characteristics of all of the known polymorphs of torsemide. Physical characteristics must be provided that are sufficient to distinguish the polymorphs from other torsemide polymorphs and from nonpolymorphic torsemides. The specification also did not provide any working examples of torsemide polymorphs. Therefore, the invention was not adequately described, and it is not clear whether or not the inventor was in "possession" of the invention at the time the application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 6-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A. Regarding claims 1-2, 6-14, the phrase "if desired" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

- B. In claim 14, line 1, page 10, the phrase "known polymorphs" is indefinite. What polymorphs is the applicant claiming?
- C. In claim 1, line 2, page 9, the term "II" is indefinite since the chemical formula for this compound is not depicted. The chemical formula for this compound must be depicted at the claim.
- D. In claim 3, lines 1-2, the terms "II" and "I" are indefinite because the structures for "II" and "I" are not recited at the claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 3 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Gutman et. al. At page 33, see example 3.

Claim 5 is objected to because it is based on a rejected claim.

The IDS filed 8/2/2004 has been considered. The references that have been crossed out will not be considered until the translations are provided to the examiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.

BMR September 7, 2004 Supervisory Patent Examiner
Technology Center 1600